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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/751,346

01/02/2004

Ron S. Israeli

41426-FA-PCT-US/JPW/CY

7618

57539 7590 11/18/2008
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EXAMINER

YAO, LEI

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

11/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/751,346	Applicant(s) ISRAELI ET AL.	
	Examiner LEI YAO	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/25/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23-25,27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23-25,27,29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment and Arguments

The Amendment filed on 8/25/2008 in response to the previous Non-Final Office Action (2/22/2008) is acknowledged and has been entered.

Claims 1-20, 22, 26, 28, and 32-58 are cancelled.

Claims 21, 23-25, 27, 29-31 are pending and examined for a method of eliminating cancerous prostate epithelial cells comprising providing an antibody coupled to a cytotoxic agent which antibody binds to an outer membrane domain of PSMA (SEQ ID NO:128)

Rejections Withdrawn

1. The new matter rejection of claims 21, 23-25, 27, and 29-31 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments to the claims.

Rejections/Rejections Maintained and Response to Applicant's Arguments

Priority:

The Office remains giving currently filing date, 1/2/2004, for the instant claims 21, 23-25, and 27-31 as set forth in the Office action dated 2/22/2008.

Applicant argues: the prior filed PCT/US96/02424 (filed on 2/23/1996) that the current application is priority to has provided supports:

at page 32, lines 23 to page 33, line 2, which discloses selecting hydrophilic amino acid sequences to generate antibodies;

page 32, lines 14 to 17 of the specification recites that 'with the protein sequence information, antigenic areas may be identified and antibodies directed against these

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areas may be generated and targeted to the prostate cancer for imaging the cancer or therapies;

the specification state that the "antigen has the characteristics of a membrane spanning protein with the majority of the protein on the exofacial surface" at page 60, lines 18-21;

the specification state at page 62, lines 16-18 "[a]ntibodies against PSM antigen coupled with a cytotoxic agent will be useful to eliminate prostate cancer cells.

In response, the Office agrees the application of PCT teaches that the PSMA protein is hydrophilic membrane protein and contemplates antibodies to the hydrophilic amino acids of the protein and the protein coupled to a cytotoxic protein useful to eliminate prostate cancer cells. However, the claimed invention is drawn to a method of using an antibody specific to the hydrophilic amino acids in the outer member of the protein, Applicant would clearly know how many hydrophilic amino acids in this PSMA protein, they would not be limited to the outer member of the protein. The PCT application does not define that the hydrophilic amino acids are restricted in the outer membrane of the protein, not in the cytosolic portion or in the transmembrane domain of the protein. Thus, what has been contemplated in the PCT application encompasses different scope as current claimed invention, therefore, does not support claimed method of eliminating cancerous prostate epithelial cells comprising providing an antibody binding to an outer membrane domain of prostate specific membrane antigen (SEQ ID NO: 128). Further, agent binding to the outer member of PSMA to eliminate the prostate cancer is never been mentioned in this PCT application.

Applicant further argues that the requirement for the antibody specifically to bind to the outer membrane of the protein as recited in the claimed method is additional requirement regarding support (page 5, last paragraph). In response, claimed method

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of eliminating cancerous prostate epithelial cells requires an antibody to the outer membrane of the PSMA protein, which has not been disclosed and/or contemplated in the prior application as discussed above. The requirement for a support of current claimed method of using an antibody to the outer membrane is not an additional. If the prior application does not disclose an antibody to the outer membrane, how can late filed applications claim use of this antibody?

Rejection under 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 21, 23, 25, 27, and 29-31 remain rejected under 35 U.S.C. 102 (b) as being anticipated by Murphy et al., (WO9947554, Publication Date 9/23/1999) evidenced by sequence search result as set forth in the previous Office action.

This rejection is remained because of the application claiming the priority to the PCT/US96/02424 is not given for the reason discussed above. Applicant does not argue the content of the rejection in the remarks.

2. Claims 21, 23-25, 27, and 29-31 remain and again rejected under 35 U.S.C. 102(b) as being anticipated by Horoszewicz et al., (US Patent, 5162504, Nov,

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1992) as evidenced by Horoszewicz et al., (Anticancer Res, vol 7, page 927-35, 1987) and Murphy et al., (WO9947554, Publication Date 9/23/1999).

Applicant argues that neither the 5162504 patent, nor the article Horoszewicz et al., states the antibody 9H10-A4 binding to an outer membrane domain of PSMA. In response, first, as stated in the rejection below:

....in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences.

Applicant does not provide any evidence showing that the antibody 9H10-A4 does not bind to an outer membrane domain of PSMA.

Second, Horoszewicz et al. has shown that 9H10-A4 antibody binds only to the surface of prostate cancer cell LNCaP that expresses PSMA on the surface. The instant specification on paragraph [0010] cites the reference of Horoszewicz et al., and states:

[0010] Prostate-specific membrane antigen (PSM) which appears to be localized to the prostatic membrane has been identified. This antigen was identified as the result of generating monoclonal antibodies to a prostatic cancer cell, LNCaP (Horoszewicz et al).

Thus, the PSM antigen is cloned from LNCaP prostate cancer cell and identified as expressed on the surface of the cell in the instant application.

Third, many early or late published articles cite Horoszewicz et al., (Anticancer Res) and state that the antibody 9H10-A4 recognizes PSMA expressed on the surface LNCaP cell. The references can be provided upon Applicant's request.

Rejection under 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23-25, 27, and 29-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Horoszewicz et al (US Patent, 5162504, Nov, 1992) in view of Liu et al (Cancer Research. Vol 57, page 3629-34, 1997) as evidenced by sequence search result and Israeli et al (Cancer Res. vol 53, page 227-230, 1993).

Applicant again argues the priority and states that Liu (1997) published after the filing date of PCT/US96/02424 that the instant application claims priority to. The claimed priority has been discussed above and filing date for the claimed method is given 1/2/2004. Thus, Applicant's arguments have not been found persuasive, and the rejections are maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643